



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Membership Forms for Organ Procurement and Transplantation Network, OMB No. 0915-0184 - Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-9094.

SUPPLEMENTARY INFORMATION: *Information Collection Request Title:* Membership Forms for Organ Procurement and Transplantation Network, OMB No. 0915-0184 – Revision.

Abstract: Membership in the Organ Procurement and Transplantation Network (OPTN) is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.; the OPTN final rule, 42 CFR part 121; OPTN policies; and OPTN bylaws. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8, requires that hospitals in which transplants are performed by members of, and abide by, the rules and requirements of the OPTN (that have been approved by the Secretary of Health and Human Services) as a condition of participation in Medicare and Medicaid.

A 60-day notice was published in the *Federal Register*, 87 FR 52389 (Aug.25, 2022). There were no public comments.

Need and Proposed Use of the Information: The application materials are needed to ensure that all members and prospective members of the OPTN submit evidence that they meet the required qualifications for membership. These materials provide the OPTN with information to permit the OPTN to confirm and demonstrate that applicants meet OPTN membership application requirements, and to create a record of the application review process and resulting actions for consideration by the Secretary of Health and Human Services if an applicant subsequently appeals a membership rejection by the OPTN.

This is a request to revise the current OPTN data collection associated with transplant hospitals, organ procurement organizations, transplant histocompatibility laboratories, medical/scientific and public organizations, business organizations, and individuals to meet or sustain requirements for OPTN membership to include data collection forms for OPTN member hospitals requesting HIV Organ Policy Equity (HOPE) Act variances as well as the Kidney Paired Donation Pilot Program (KPDPP) contact update form. HRSA is submitting the

following changes to the membership forms to clarify requirements and eliminate redundancy while adding more explanatory language and instruction to the applications, which include:

- (1) Adding two new data collection forms for HOPE Act Variance Request and KPDPP contact update form. The HOPE Act Variance Request is for any OPTN member transplant program that wishes to start a variance to receive HIV-positive organs for their HIV-positive patients. The KPDPP contact update is a form that indicates contact information for programs participating in the KPDPP.
- (2) Adding three standalone forms for data collection: Primary Program Administrator, Primary Data Coordinator, and Additional Surgeon and Physician. All three of these forms include data previously collected on other OMB-approved forms in this package, but now will be standalone forms for greater ease of use for the applicant.
 - The Primary Program Administrator data collection form includes data previously collected in each organ-specific application form. Users will only have to complete one form if the proposed Primary Program Administrator serves in that role for multiple programs.
 - The Primary Data Coordinator collection form includes data previously collected in each organ-specific application form. This form will be used for organ procurement organizations, histocompatibility lab members, and organ transplant programs so that one standalone form will serve all three member types.
 - The Additional Surgeon and Physician data collection form includes data previously collected in the Certificate of Assessment and Program Coverage Plan (COA/PCP) Membership Application form. Users will only have to complete one form if the proposed Surgeon and Physician serve in that role for multiple programs.

The organ-specific application forms have been revised to include the information found in the COA/PCP, which has been embedded into all of the organ-specific application forms, negating the need for an independent data collection form.

Likely Respondents: New and existing transplant hospitals, organ procurement organizations, histocompatibility laboratories, medical/scientific organizations, public organizations, businesses, and individual members.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The total burden hours in the OMB inventory increased by 944 hours from the previously OMB-approved data collection package from August 20, 2020. This increase is due in part to including new membership forms.

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents ¹	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
OPTN Membership Application for Transplant Hospitals and Programs	251	0.28	71	4.00	284
OPTN Membership Application for Kidney Transplant Programs	234	0.56	132	8.00	1,056

OPTN Membership Application for Liver Transplant Programs	143	0.59	85	13.00	1,105
OPTN Membership Application for Pancreas Transplant Programs	120	0.26	32	13.00	416
OPTN Membership Application for Heart Transplant Programs	145	0.34	50	20.50	1,025
OPTN Membership Application for Lung Transplant Programs	72	0.64	47	9.00	423
OPTN Membership Application for Islet Transplant Programs ²	19	0.00	0	5.00	0
OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	43	0.98	43	15.50	667
OPTN Membership Application for Intestine Transplant Programs	21	0.19	4	11.00	44
OPTN Membership Application for Organ Procurement Organizations (OPOs)	57	0.14	8	40.00	320

OPTN Membership Application for Histocompatibility Laboratories	141	0.21	30	2.50	75
OPTN Representative Form	1,760	0.02	36	0.25	9
OPTN Medical/Scientific Membership Application	10	0.30	3	0.75	3
OPTN Public Organization Membership Application	7	0.57	4	0.50	2
OPTN Business Membership Application	11	0.55	7	0.88	7
OPTN Individual Membership Application	8	0.88	8	0.25	2
OPTN Membership Application Surgeon or Physician Log ³	0	0.00	0	0.00	0
Primary Program Administrator Form	1,562	0.05	79	0.25	20
Primary Data Coordinator Form	1,760	0.03	53	0.13	7
Additional Surgeon and Physician Request Form	1,562	0.08	125	1.17	147
HOPE Act Variance Request Form ⁴	68	0.00	0	1.33	0
Kidney Paired Donation Pilot Program (KPDPP) contact update form	159	0.33	53	1.63	87
Total = 22 forms	8,153		870		5,699

1. The numbers of respondents were updated with the data as of December 31, 2021, and reflect changes in

- members' statuses.
2. There were no Islet applications processed in 2021, hence no responses.
 3. The OPTN Membership Application Surgeon or Physician Log is an optional form. The information can also be submitted by the OPTN member using a different format. The burden to complete is built into the organ application data.
 4. There were no HOPE Act Variance Request forms processed in 2021, hence no responses.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

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Director, Executive Secretariat.

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